

Figure 1

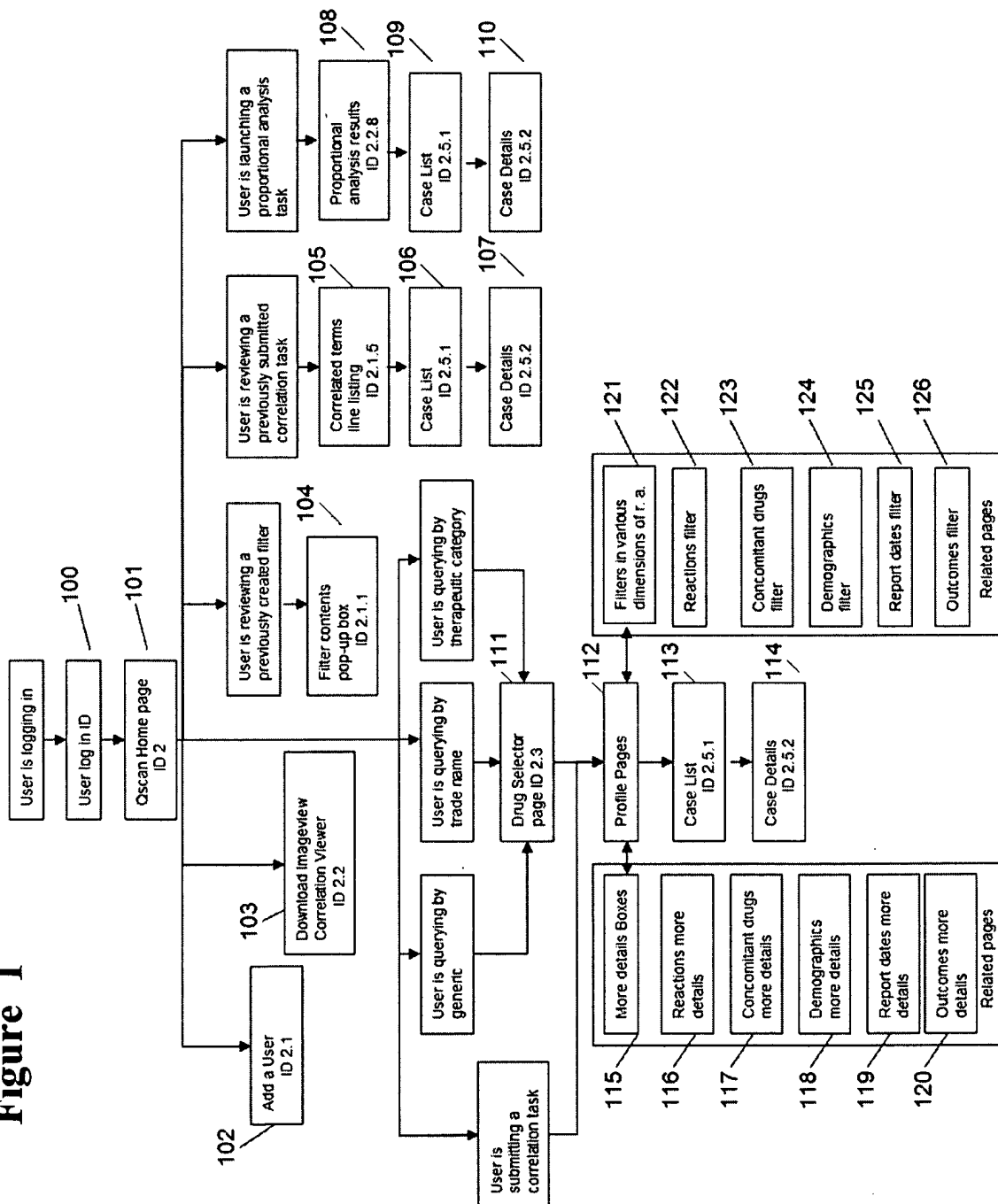


Figure 2

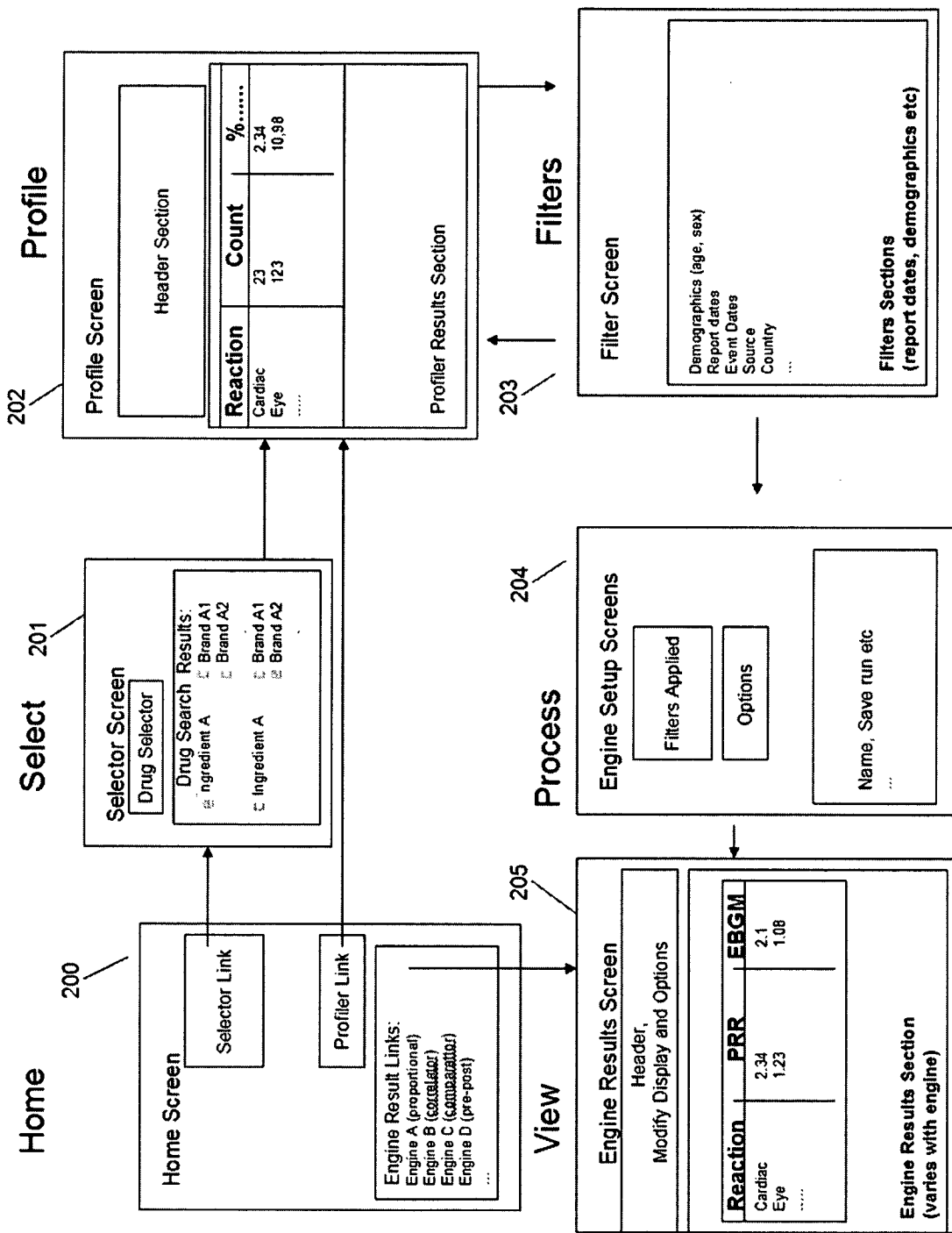


Figure 3

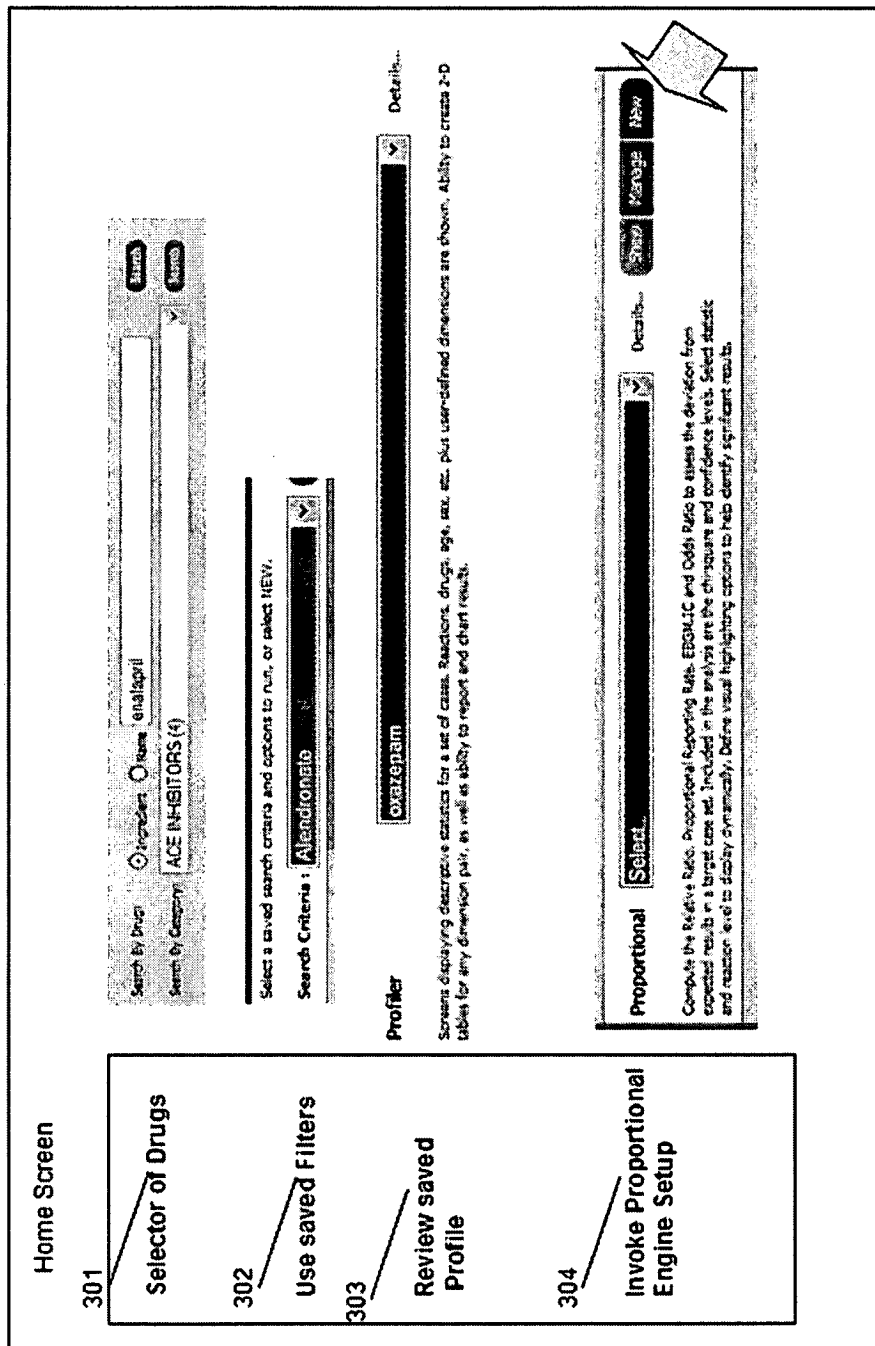


Figure 4

Filter Screen

401	Summary	Search Criteria Details	
400	Drugs (details)	Search Criteria Items: Alendronate 396	(Drug Legend: A=All, S=Subject, I=Ingredient, R=Drug Name)
402	Reactions (details)	Criteria	Value
403	Demographics	Included Ingredients	ALENDRONATE SODIUM (A)
404	Report Dates	Drug boolean	((ALENDRONATE SODIUM)) [DO NOT MATCH OFF]
	Event Dates	Reactions	all [INCLUDED]
	Outcomes	Demographics	all
	Report Sources	Report Dates	From Feb 1, 1995 To Mar 6, 1996
	Report Types	Event Dates	all
	Case Sources	Included Outcomes	CONGENITAL ANOMALY, DEATH, DISABILITY
	Excluded Cases	Report Sources	all
	Excluded Duplicate Cases	Report Types	all
	Notes	Case Sources	all
		Excluded Cases	none
		Excluded Duplicate Cases	off

Figure 5

Query Screen

500 (Generic, or 'ingredient') 501 (Trade name)

503 (Therapeutic Category)

Search By Drug: ☐ Ingredient ☐ Name

Search By Category: ACE INHIBITORS (4)

4 trade(s) matched

Ingredients (all suspect)	Names (Show all names)
ENALAPRIL MALEATE (1, 0)	<input type="checkbox"/> ENALAPRIL MALEATE TABLETS (1, 0)
LISINPAPRIL (13, 6)	<input type="checkbox"/> LISINPAPRIL TABLETS (12, 6) <input type="checkbox"/> LISINPAPRIL TABLETS (1, 0)
HYDROCHLOROTHIAZIDE, TELMISARTAN (0, 0)	<input type="checkbox"/> MICARDIS HCT TABLETS (4, 0)

To view drug list and define logical rules, click "Detailed Search"

No. of Ingredients Searched: 0  
 No. of Drugs Selected: 0

Review Selection and Set Default Options

Figure 6

DATA PEDIGREE Screen							
600	601	602	603	604	605	606	607
MAPTO	VERBATIM	SOURCE	INCIDENTS	CASE COUNTS	PROCESSING	Cross reference	FIRST/LAST
PROZAC	PROZAC	SRS	17933	17933	A	Orange Book	1/27/69 - 12/2/97
PROZAC	PROZAC	AERS	3309	3309	A	Orange Book	11/1/89 - 6/2/99
PROZAC	PROZAC (SUOX)	AERS	2	2	M	NDCD	2/27/69 - 2/2/97
FLUOXETINE	FLUOXETINE FOL	AERS	122	122	M	Orange Book	6/27/69 - 1/2/97
ETC....							

## Figure 7

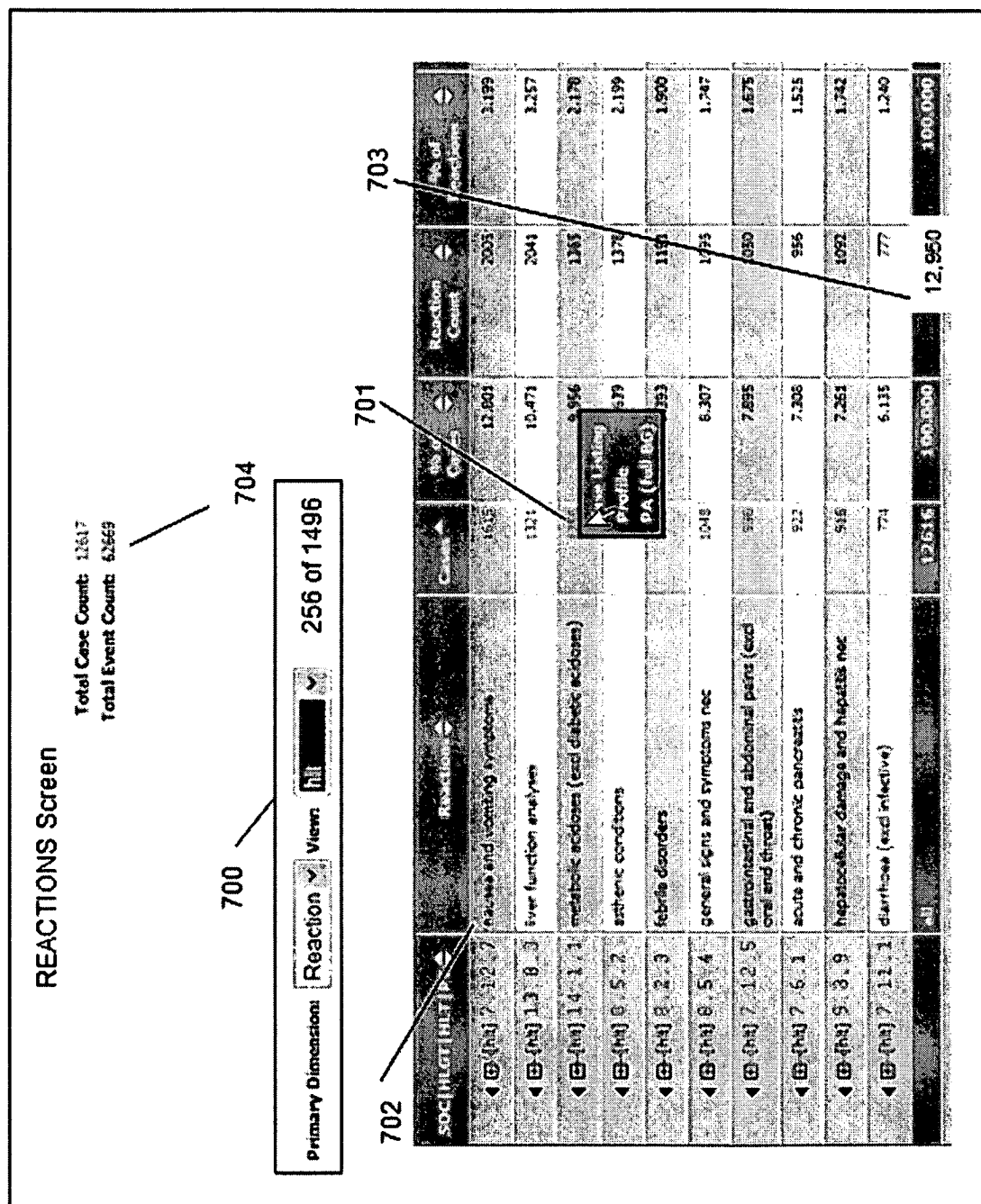


Figure 8

**DRUGS Screen**

Total Case Count: 11617

Primary Dimension:

800	801	802
Drugs	Case Count	Case Count
<input type="checkbox"/> STAYLONE	12,577	150,029
<input type="checkbox"/> LAMOTRIGINE	7,731	61,274
<input type="checkbox"/> DEBAROSIDE	1,597	25,777
<input type="checkbox"/> INDIANIN SULFATE	8,074	18,541
<input type="checkbox"/> RITONAVIR	3,299	18,147
<input type="checkbox"/> SIALAMETHANOL	7,007	21,056
<input type="checkbox"/> TURETHOTON	2,004	22,577
<input type="checkbox"/> NEUFRAVINE MESTATE	2,442	19,355
<input type="checkbox"/> NEUTRAPINE	2,215	16,372
<input type="checkbox"/> EFANEDAZ	1,146	17,029
<b>Total</b>	<b>11617</b>	<b>100,000</b>

## Figure 12

**Reaction Filter Screen**

Search Reactions:

**Invert Reactions** **Collapse Reaction Tree** **Detailed Setup**

**Find Next** **Reset**

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**Reactions**

- ☒ [SOG] blood and lymphatic system disorders
  - ☒ [HLGT] anaemias non-haemolytic and marrow depression
  - ☒ [HLGT] bleeding tendencies and purpura (excl thrombocytopenic)
    - ☒ [HLT] bleeding tendencies
      - ☐ [PT] bleeding tendency
      - ☐ [PT] haemorrhagic disease of newborn
      - ☒ [PT] haemorrhagic disorder
    - ☒ [HLT] purpura (excl thrombocytopenic)
      - ☒ [HLGT] coagulopathies and bleeding diatheses
      - ☒ [HLGT] haematological disorders nec
      - ☒ [HLGT] haematopoietic neoplasms (excl leukemias and lymphomas)
      - ☒ [HLGT] haemoglobinopathies
      - ☒ [HLGT] haemolysis and related conditions
      - ☒ [HLGT] leukaemias
      - ☒ [HLGT] platelet disorders
      - ☒ [HLGT] red blood cell disorders
      - ☒ [HLGT] spleen, lymphatic and reticuloendothelial system disorders
      - ☒ [HLGT] white blood cell disorders
- ☒ [SOG] cardiac disorders
- ☒ [SOG] congenital, familial and genetic disorders

Figure 13

Correlation Screen										1303		Rank
1305	1300	1301	1306	1304	1307	1308	1309	1310	1311	1312	1313	
Drug	Category	Term 1	Term 2	Category	Score	Case Counts	DF	Confidence Level				
<input checked="" type="checkbox"/> CANDESARTAN CILEXETIL						2557	12317364	99.99				1
<input type="checkbox"/> B - Sex						2557	12317364	99.99				14
Female	Drugs	CANDESARTAN CILEXETIL	Female	Sex		2557	12317364	99.99				234
Male	Drugs	CANDESARTAN CILEXETIL	Male	Sex		2025	9753556	99.98				...
Sex Not Specified	Drugs	CANDESARTAN CILEXETIL	Sex Not Specified	Sex	0.2222	211	1142103	99.96				2
<input type="checkbox"/> Demographics						2492	12004129	99.97				23
Age 51 to 75 Years	Drugs	CANDESARTAN CILEXETIL	Age 51 to 75 Years	Demographics		1016	4891253	99.97				45
Age over 75 Years	Drugs	CANDESARTAN CILEXETIL	Age over 75 Years	Demographics	0.4591							67
Age Not Specified	Drugs	CANDESARTAN CILEXETIL	Age Not Specified	Demographics	0.3966	785	3655315	99.97				
Age 31 to 50 Years	Drugs	CANDESARTAN CILEXETIL	Age 31 to 50 Years	Demographics	0.3340	507	2438414	99.97				

Figure 14

Correlation Case List Details Screen

Case ID	Sex	Medical Record Control Code	FDA Report Receipt Date	Age	Drug	Relationship	Outcomes	Reporting Country	Tracking
1401 405405	U	2003A000355	2003/03/14	0	ATACAND	convulsions nos. drug exposure via breast milk	REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE		<input checked="" type="checkbox"/>
1402 454609	M	2004U0006149	2005/01/03	0	ATACAND, HYDROCHLOROTHIAZIDE, SYNTHROID	drug exposure during pregnancy, fortanide to leg, jaundice neonatal oligohydramnios, ultrasound antenatal screen abnormal, ultrasound kidney abnormal	REQUIRED INTERVENTION TO PREVENT PERMANENT IMPAIRMENT/DAMAGE		<input checked="" type="checkbox"/>
1403 3041306	F	20000500073	2001/01/02	14	ATACAND, ATACAND	nil discoloration, tooth discoloration, tremor	OTHER		<input checked="" type="checkbox"/>
1404 3356447	M	2001U0005707	2001/07/05	2	ATACAND	accidental exposure	OTHER		<input checked="" type="checkbox"/>
1405 5002136	M	JP-ROCHE-379025	2004/12/09	9	ROCEPHIN, FAMOTIDINE, DELTIAZEM, CLARITHROMYCIN, COMELIAN, BLOPRESS, URSO	cholecystitis chronic nos. cholelithiasis	OTHER		<input checked="" type="checkbox"/>
1406 405402	M	2003SE00411	2003/02/13	14	BLOPRESS	hemodialysis, renal failure acute	HOSPITALIZATION INITIAL OR		<input checked="" type="checkbox"/>

## Figure 15

Case ID:	34135																																							
Sex:	F																																							
Age:	14 years 0 months																																							
Weight:	None																																							
Death Date:	None																																							
Reactions:	<table border="1"> <thead> <tr> <th>As Reported</th> <th>Onset Date</th> <th>Preferred Term</th> <th>High Level Term</th> <th>System Organ Class</th> </tr> </thead> <tbody> <tr> <td>Nail Discoloration</td> <td>---</td> <td>nail discoloration</td> <td>nail and nail bed conditions (and infections and infections)</td> <td>skin and subcutaneous tissue disorders</td> </tr> <tr> <td>Tooth Discoloration</td> <td>---</td> <td>tooth discoloration</td> <td>dental surface disorders</td> <td>gastrointestinal disorders</td> </tr> <tr> <td>Tumor Rec</td> <td>---</td> <td>tumor</td> <td>tumor (well circumscribed)</td> <td>musculoskeletal disorders</td> </tr> </tbody> </table>	As Reported	Onset Date	Preferred Term	High Level Term	System Organ Class	Nail Discoloration	---	nail discoloration	nail and nail bed conditions (and infections and infections)	skin and subcutaneous tissue disorders	Tooth Discoloration	---	tooth discoloration	dental surface disorders	gastrointestinal disorders	Tumor Rec	---	tumor	tumor (well circumscribed)	musculoskeletal disorders																			
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Tooth Discoloration	---	tooth discoloration	dental surface disorders	gastrointestinal disorders																																				
Tumor Rec	---	tumor	tumor (well circumscribed)	musculoskeletal disorders																																				
Comorbidities:	<table border="1"> <thead> <tr> <th>As Reported</th> <th>Name</th> <th>Dose</th> <th>Route</th> <th>Drug Role</th> <th>Overdose</th> <th>Rechallenge</th> <th>Therapy Started Date</th> <th>Therapy Duration</th> <th>Days to Onset</th> <th>Indication</th> <th>Lot Number</th> <th>Expiration Date</th> </tr> </thead> <tbody> <tr> <td>Ataxia</td> <td>ATACARD</td> <td>15 MG QD PO</td> <td>ORAL</td> <td>Primary Support Drug</td> <td>Positive dechallenge</td> <td>Does not apply</td> <td>03 Aug 2000</td> <td>---</td> <td>---</td> <td>---</td> <td>---</td> <td>---</td> </tr> <tr> <td>Ataxia</td> <td>ATACARD</td> <td>15 MG QD PO</td> <td>ORAL</td> <td>Secondary Support Drug</td> <td>Positive dechallenge</td> <td>Does not apply</td> <td>03 Aug 1999</td> <td>---</td> <td>---</td> <td>---</td> <td>---</td> <td>---</td> </tr> </tbody> </table>	As Reported	Name	Dose	Route	Drug Role	Overdose	Rechallenge	Therapy Started Date	Therapy Duration	Days to Onset	Indication	Lot Number	Expiration Date	Ataxia	ATACARD	15 MG QD PO	ORAL	Primary Support Drug	Positive dechallenge	Does not apply	03 Aug 2000	---	---	---	---	---	Ataxia	ATACARD	15 MG QD PO	ORAL	Secondary Support Drug	Positive dechallenge	Does not apply	03 Aug 1999	---	---	---	---	---
As Reported	Name	Dose	Route	Drug Role	Overdose	Rechallenge	Therapy Started Date	Therapy Duration	Days to Onset	Indication	Lot Number	Expiration Date																												
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Ataxia	ATACARD	15 MG QD PO	ORAL	Secondary Support Drug	Positive dechallenge	Does not apply	03 Aug 1999	---	---	---	---	---																												
Outcomes:	OTHER(OT)																																							
Event Date:	None																																							
Sending Manufacturer:	Astrucor Pharmaceuticals LP																																							
Manufacturer Control Code:	220030072																																							
Manufacturer Date:	12 Sep 2000																																							
Report Code:	Periodic																																							
Report Source:	Health Professional																																							
Case Source:	None																																							
Remarks:																																								

## Figure 16

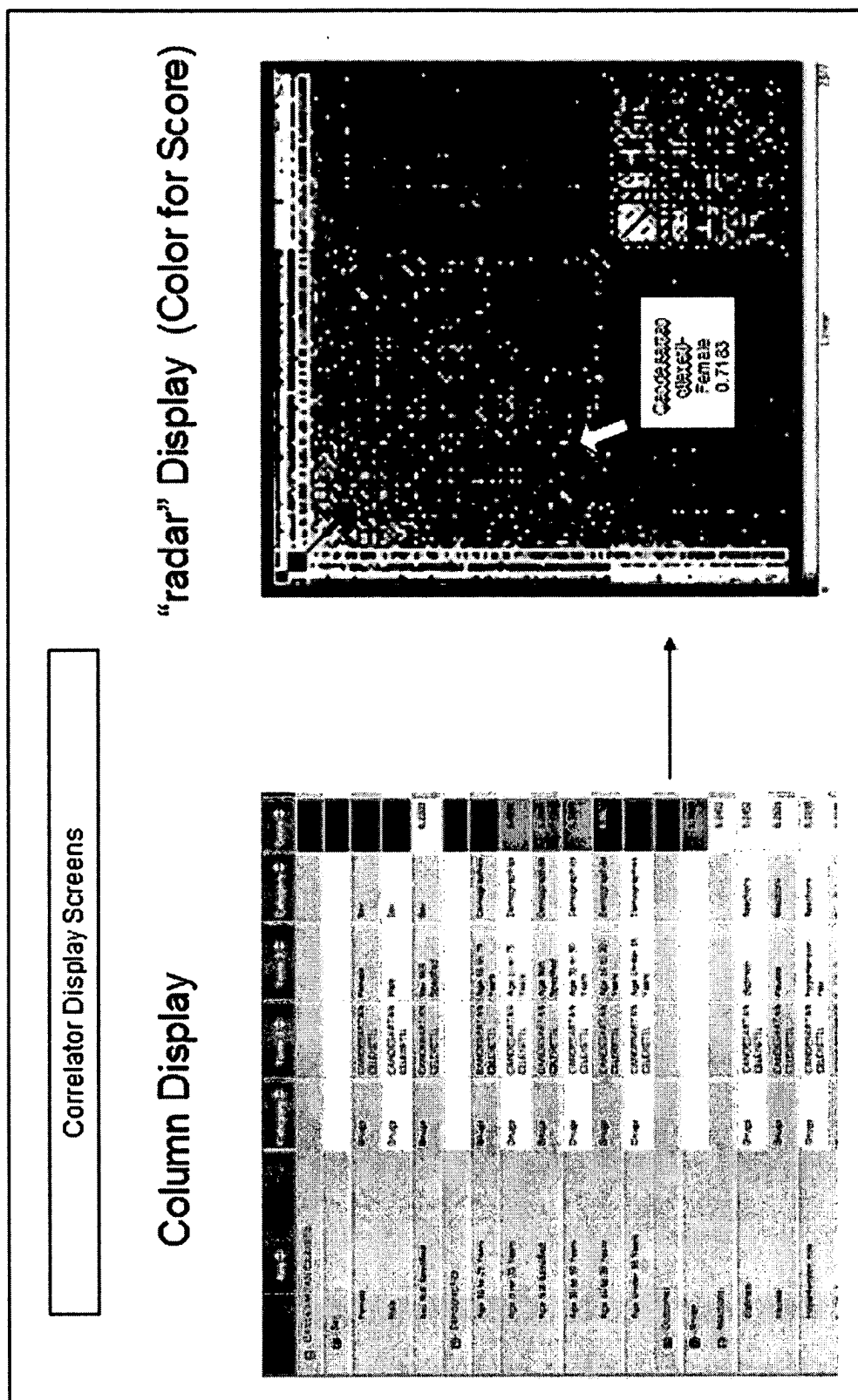
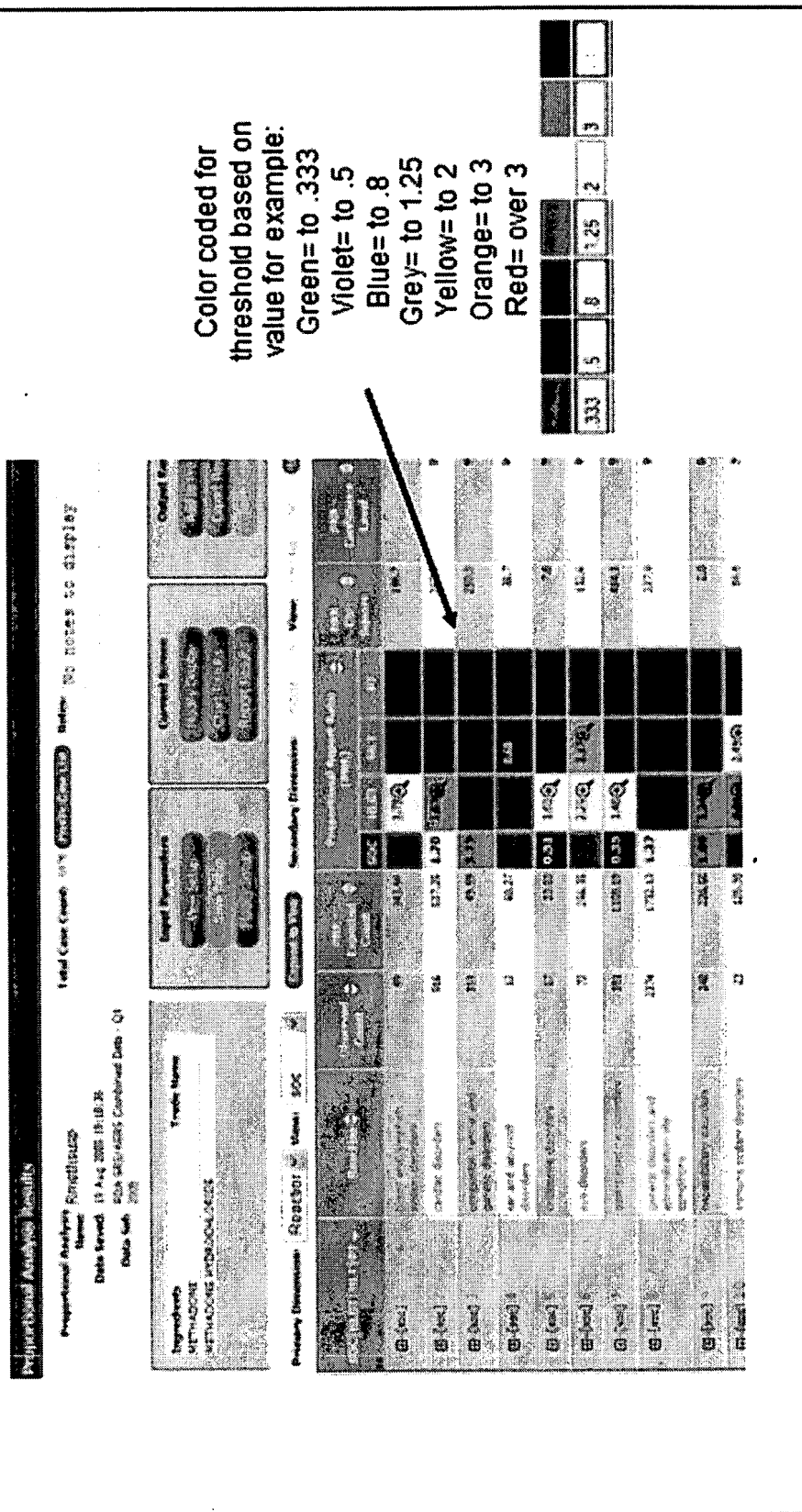


Figure 17

Proportional Display Screen: Matrix



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Figure 18

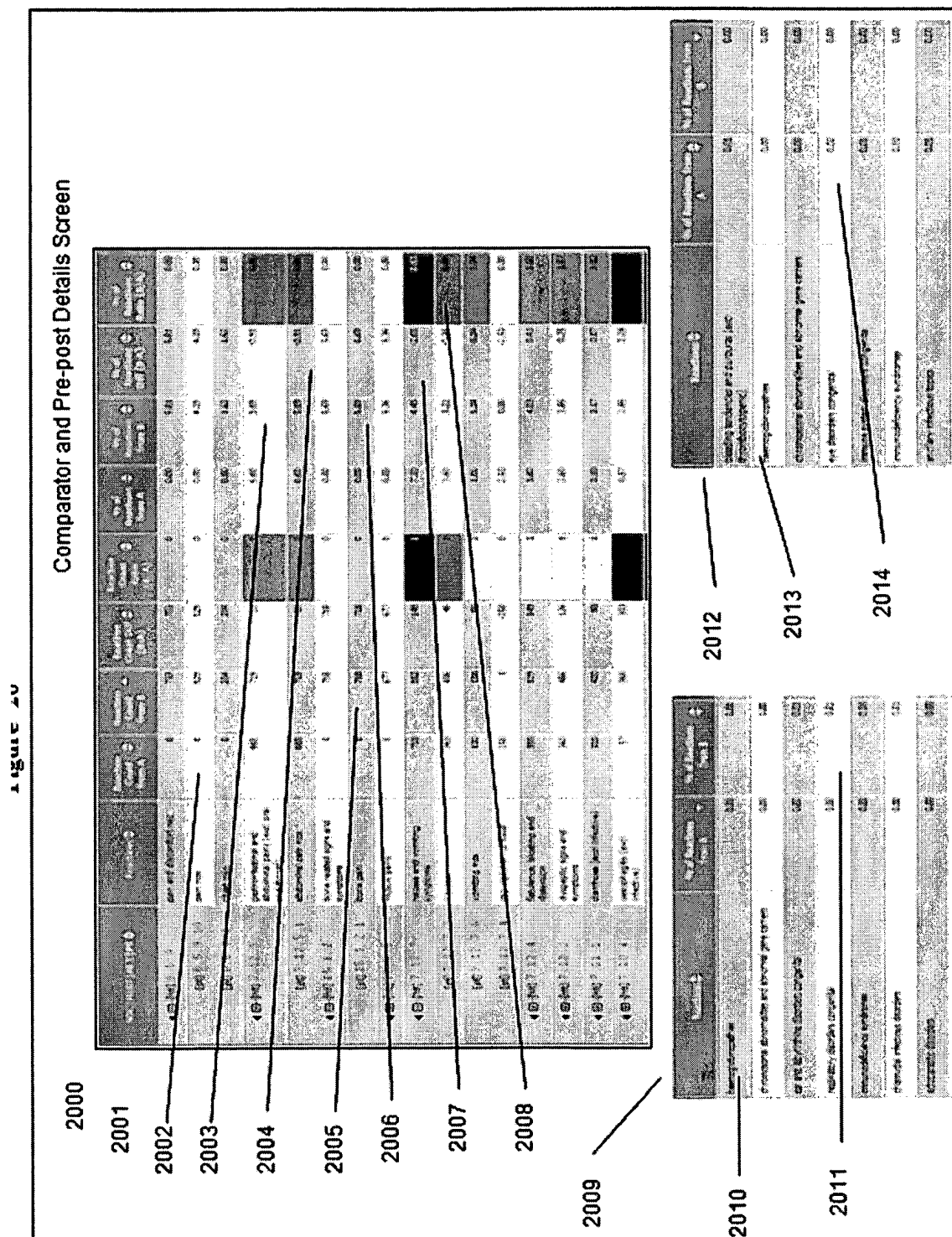
Proportional Display Screen: Detail				
1800 —	Drug	AMLODIPINE BESYLATE		
1801 —	Reaction	Surgical and medical procedures		
1802 —	Reaction Count	927		
1803 —	Expected Reaction Count	201.02		
1804 —	Relative Rate	4.61		

Figure 19

Proportional Display Screen: line

1901	1900	1902	1903	1904
Drug	Reactions	Events	RR Expected Count	Relative Risk (RR)
		51001	0.00	
		53091	5.00	
ASACAVIR SULFATE	blood and lymphatic system disorders	11	12.14	0.61
ABECIXIMAB	blood and lymphatic system disorders	300	44.25	
ACARBOSE	blood and lymphatic system disorders	25	5.91	2.92
ACEBUTOLOL HYDROCHLORIDE	blood and lymphatic system disorders	12	10.75	1.12

## Figure 20



## Figure 21

[illegible]